

# EXHIBIT 1

## **PRESCRIPTION DRUG MARKETING ACT OF 1987**

*P.L. 100-293, see page 102 Stat. 95*

### **DATES OF CONSIDERATION AND PASSAGE**

*House: May 4, 1987*

*Senate: March 31, 1988*

**House Report (Energy and Commerce Committee) No. 100-76,**

**Apr. 30, 1987 [To accompany H.R. 1207]**

**Senate Report (Finance Committee) No. 100-303,**

**Mar. 18, 1988 [To accompany H.R. 1207]**

**Cong. Record Vol. 133 (1987)**

**Cong. Record Vol. 134 (1988)**

*The Senate Report is set out below and the Signing Statement of the President (page 71) follows.*

### **SENATE REPORT NO. 100-303**

[page 1]

The Committee on Finance, to which was referred the bill (H.R. 1207) to amend the Federal Food, Drug, and Cosmetic Act to ban the reimportation of drugs produced in the United States, to place restrictions on the distribution of drug samples, to ban certain resales of drugs by hospitals and other health care facilities, and for other purposes, having considered the same reports favorably thereon and recommends that the bill do pass.

\* \* \* \* \*

### **I. SUMMARY**

H.R. 1207 makes changes in the national drug distribution system. The bill prohibits the reimportation of prescription drugs except by the manufacturer or for emergency use, bans the sale, trade or purchase of drug samples, prohibits with certain exceptions the resale of prescription drugs purchased by health care entities for their own use, mandates storage, handling and accounting requirements for drug samples, prohibits the wholesale distribution of drugs in interstate commerce from states which do not license wholesalers or whose licensing requirements do not meet minimum

[page 2]

standards, and establishes a range of criminal and civil penalties for violations of these provisions.

The purpose of the legislation is to curb operation of the diversion market for prescription drugs that operates outside of normal channels of distribution and makes it difficult to protect American consumers from mislabeled, subpotent, adulterated, expired, or counterfeit pharmaceuticals.

**LEGISLATIVE HISTORY**  
**SENATE REPORT NO. 100-303**

**II. COMMITTEE ACTION ON THE BILL**

The Senate counterpart to H.R. 1207, S. 368, was introduced on January 21, 1987, and was referred to the Committee on Finance. Hearings on that bill were held before the Subcommittee on International Trade on June 15, 1987. Following passage of H.R. 1207 by the House of Representatives on May 4, 1987, that bill also was referred to the Committee on Finance.

**III. GENERAL EXPLANATION**

A significant volume of pharmaceuticals is being reimported to the United States as American Goods Returned. These goods present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. Moreover, the hazards associated with reimports have forced the Food and Drug Administration and the U.S. Customs Service to spend inspectional and other resources that are sorely needed in other areas.

The distribution of drug samples to patients by practitioners licensed to dispense pharmaceuticals is a useful and valuable medical tool. The bill is designed to retain the positive benefits of samples while providing for improved storage and handling, greater accountability and strong penalties for unauthorized distribution.

The resale of prescription drugs by health care entities to persons outside the corporate umbrella of the institution—such as a wholesaler—helps fuel the diversion market, and, with certain exceptions, is prohibited by this bill.

**SECTION 1—SHORT TITLE**

Subsection (a) provides that the Act may be cited as the "Prescription Drug Marketing Act of 1987." Subsection (b) provides that all amendments or repeals are to the Federal Food, Drug and Cosmetic Act (FDCA).

**SECTION 2—FINDINGS**

This section contains findings regarding the threat to the public health posed by prescription drug diversion and counterfeiting. These findings form the basis for amending the FDCA to ensure the safety and efficacy of the prescription drug supply of the United States by restricting or prohibiting certain distribution practices.

**SECTION 3—REIMPORTATION**

This section amends Section 801 of the FDCA to prohibit the reimportation of U.S.-produced pharmaceuticals except by the man-

[page 3]

ufacturer of the product or as authorized by the Secretary of Health and Human Services for emergency purposes.

Reimported pharmaceuticals threaten the American public health in two ways. First, foreign counterfeits, falsely described as reimported U.S.-produced drugs, have entered the distribution system. Second, proper storage and handling of legitimate pharma-

# EXHIBIT 2

100TH CONGRESS  
1st Session

HOUSE OF REPRESENTATIVES

REPORT  
100-76

## PRESCRIPTION DRUG MARKETING ACT OF 1987

APRIL 30, 1987.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce,  
submitted the following

### REPORT

[To accompany H.R. 1207]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce to whom was referred the bill (H.R. 1207) to amend the Federal Food, Drug, and Cosmetic Act to ban the reimportation of drugs produced in the United States, to place restrictions on the distribution of drug samples, to ban certain resales of drugs by hospitals and other health care facilities, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

A significant volume of pharmaceuticals is being reimported to the United States as American Goods Returned. These goods present a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. The ready market for reimports has also been a catalyst for the perpetration of a continuing series of frauds against American manufacturers, and has provided the cover for the importation of counterfeit pharmaceuticals in several cases. Moreover, the hazards associated with reimports have forced the Food and Drug Administration and the U.S. Customs Service to spend inspectional and other resources that are solely needed in other areas.

The existing system of providing samples of pharmaceutical products to physicians through manufacturers' sales representatives invites abuse. The approximately eighty felony pleas obtained by the United States Attorney in Atlanta, many of which related directly to the misuse of drug samples, are but the latest episode in a long history of misuse. Samples that are improperly sold, bartered, or exchanged often end up in the secondary market, where they become adulterated, misbranded or both. The propensity for misbranded sample merchandise to appear in the diversion market also makes it easier for expired or counterfeit pharmaceuticals to be introduced into the wholesale distribution system. The production and distribution of samples, as well as efforts to police sales representatives, are costs that must be recouped by manufacturers in the sales price of regular products.

The distribution of drug samples to patients by practitioners licenses to dispense pharmaceuticals is a useful and valuable medical tool. As noted by the American Medical Association and the Pharmaceutical Manufacturers Association, the use of samples enables doctors to more quickly identify the appropriate drug therapy for a patient and at less cost. The availability of samples can also be beneficial in acute care situations and in circumstances where access to a pharmacy is difficult because of distance, time of day, lack of transportation, or the like. The Committee bill is designed to retain the positive benefits of samples while providing for improved storage and handling, greater accountability and strong penalties for unauthorized distribution.

The resale of prescription drugs by health care entities to persons outside the corporate umbrella of the institution—such as a wholesaler—helps fuel the diversion market. Such sales, which are economical only because many manufacturers sell much more cheaply to certain institutions than to wholesale customers, provide an unfair competitive advantage to any wholesaler or retailer that can obtain the preferentially priced goods. Moreover, the resales may well constitute fraud against the manufacturers, especially if the health care institution is allegedly purchasing the goods for its own use. In any case, the practice contributes to the lack of accountability as to product source in the secondary market.

#### HEARINGS

The Committees' Subcommittee on Oversight and Investigations held eight days of hearings. Two reports by the staff of the Over-

# EXHIBIT 3

## (Filed Under Seal)



# EXHIBIT 4

## (Filed Under Seal)



# EXHIBIT 5

## (Filed Under Seal)

# EXHIBIT 6

## (Filed Under Seal)

# EXHIBIT 7

23 2004

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COUNSEL FOR PLAINTIFF AND THE CLASS

BERNARD WALKER, individually,  
and on behalf of those similarly situated,

Plaintiff,

v.

TAP PHARMACEUTICAL PRODUCTS, INC.,  
ABBOTT LABORATORIES AND  
TAKEDA CHEMICAL INDUSTRIES, LTD.

Defendants.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION  
CAPE MAY COUNTY

CIVIL ACTION NO.: CPM-L-682-01

~~REDACTED~~ ORDER *Denguy*  
~~REDACTED~~ PLAINTIFF'S MOTION  
FOR PARTIAL SUMMARY  
JUDGMENT

THIS MATTER, having been brought before the Court upon the motion of plaintiff, Bernard Walker, by and through his counsel, seeking an Order granting Plaintiff's Motion for Partial Summary Judgment Pursuant to R. 4:46-1, and the Court, having considered the submissions of the parties and any arguments of counsel, and for good cause shown;

IT IS on this 27<sup>th</sup> day of April, 2003, ORDERED that Plaintiff's Motion for Partial Summary Judgment is ~~denied~~ *granted*.

~~and no further action is to be taken by the Court.~~

*Joseph C. Visalli*  
HON. JOSEPH C. VISALLI, J.S.C.

**NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE  
ON OPINIONS**

**SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION  
CAPE MAY COUNTY**

**APR 23 2004**

**TO:**

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**CASE: Bernard Walker v TAP Pharmaceutical Products, Inc., et al  
DOCKET NO: CPM L 682-01**

**NATURE OF  
APPLICATION: Partial Summary Judgment**

**MEMORANDUM OF DECISION ON MOTION  
PURSUANT TO RULE 1:6-2(f)**

Having carefully reviewed the moving papers and any response filed, I have ruled on the above motion as follows:

Under Rule 4:46-2, a moving party is entitled to summary judgment if “the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, . . . show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law.” R. 4:46-2. In Brill v. Guardian Life Ins. Co. of Am., 142 N.J. Super. 520 (1995), the Supreme Court held that the standard for whether a genuine issue of material fact exists is “whether the competent evidential materials . . . when viewed in a light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party.” Brill, 142 N.J. Super. at 540.

The New Jersey Rules of Evidence permit the introduction in a civil proceeding “of a final judgment against a party adjudging him guilty of an indictable offense in New Jersey or of an offense which would constitute an indictable offense if committed in this state. . . .” R. Evid. 803(c)(22). The opposing party may use such evidence “to prove any fact essential to sustain the judgment, unless otherwise provided by court order on acceptance of a guilty plea.” Id. cmt. Moreover, in a civil action such

evidence constitutes an admission by the party against whom it is offered. Eaton v. Eaton, 119 N.J. 628, 743-44 (1990).

While no doubt exists as to the admissibility of Defendant's plea of guilty to federal criminal charges in this civil action, Plaintiff nonetheless contends that such an admission by Defendant constitutes proof so strong and undeniable that no rational finder of fact could find in favor of Defendant. Specifically, Plaintiff claims that because of this admission by Defendant, the Court should enter partial summary judgment in favor of himself and the Class on the counts alleged in his complaint of unconscionable business practices and omissions in violation of the New Jersey Consumer Fraud Act ("CFA"), common law fraud, and civil conspiracy. Additionally, Plaintiff asserts that the doctrine of judicial estoppel bars Defendant from submitting evidence in opposition to this Motion that is inconsistent with its guilty plea.

#### Unconscionable Business Practices

The CFA prohibits any and all "unconscionable commercial practice[s], deception[s], fraud, false pretense[s], false promise[s], misrepresentation[s], or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such [acts]. . . ." N.J.S.A. 56:8-2 (alteration in original). In order to show an unconscionable business practice under the CFA, a Plaintiff must demonstrate "a violation of 'the standard of conduct contemplat[ing] good faith, honesty in fact and



observance of fair dealing.” Judge v. Blackfin Yacht Corp., 357 N.J. Super. 418, 425 (App. Div. 2003)(quoting Kugler v. Romain, 58 N.J. 522, 544 (1971)). The Court must make the determination whether the moving party has met this standard by conducting a fact-specific inquiry on a case-by-case basis. Judge, 357 N.J. Super. at 425.

#### Omissions

To show an omission under the CFA, a plaintiff must establish that the defendant 1) misrepresented or omitted a material fact; 2) knowing that such misrepresentation or omission was material; and 3) intending that another rely on the misrepresentation or omission. Zorba Contractors, Inc. v. Housing Authority, City of Newark, 362 N.J. Super. 124, 139 (App. Div. 2003).

#### Common Law Fraud

A case for common law fraud requires that a plaintiff in addition to demonstrating all the elements for an omission under the CFA show that “the other party did in fact rely on the misrepresentation or omission to its detriment.” Id. (citing Varacallo v. Mass. Mutual Life Ins. Co., 332 N.J. Super. 31, 43 (App. Div. 2000)).

#### Civil Conspiracy/Concert of Action

To establish a claim for civil conspiracy, a plaintiff must show 1) two or more

persons; 2) having an agreement with a common design; 3) as well as an unlawful purpose or a lawful purpose that the conspirators plan to achieve by unlawful means. Naylor v. Harkins, 27 N.J Super. 594, 604 (App. Div. 1953).

Plaintiff has alleged that Defendant provided to doctors free samples of Lupron® while knowing and expecting that these doctors would charge their patients for the samples, which is a violation of the federal Prescription Drug Marketing Act ("PDMA"). See 21 U.S.C. §§ 331(t), 333(b). While such evidence is sufficient to make out a *prima facie* case for an unconscionable business practice under the CFA as it shows a lack of good faith, honesty, and the observance by Defendant of standards of fair dealing, Plaintiff contends that such evidence is sufficiently strong to entitle him to summary judgment as to this charge.

There are issues of material fact as to whether the class Plaintiff and class members received a free sample and was charged for it. There are also issues related to Defendant's admission in this guilty plea because it was very carefully circumscribed to limit the admission to certain doctors and certain sales representatives. A Jury question exists on the extent of the violation of the PDMA and whether the class suffered damage. This class action does include claims based on an alleged illegal inflation of the average wholesale price (AWP).

The AWP claim if proven may be a violation of the CFA. But that issue is a

jury determination as are the elements of Common Law Fraud and Civil Conspiracy.

Judicial Estoppel

Plaintiff additionally argues that Defendant's guilty plea to the federal charges estops it from using as evidence in opposition to this Motion any position inconsistent with the one it took when entering its guilty plea. As indicated above, a guilty plea is evidence, not conclusive proof, of the facts underlying the offense. As such, the guilty plea is evidence that the distribution of free samples by a number of the sales representatives (not all) to a number of the doctors in the County and State of New Jersey (not all) knowing and encouraging the doctors to bill the patients and payor insurance companies.

In sum, the record is not so one sided that the Plaintiff should prevail on this Motion. The Motion for Summary Judgment is denied.

April 22, 2004

Joseph C. Visalli, J.S.C.

# EXHIBIT 8

STATE OF NORTH CAROLINA  
NEW HANOVER COUNTY

IN THE GENERAL COURT OF JUSTICE  
SUPERIOR COURT DIVISION  
1 CVS 5268

Harry B. Stetser, Dale E. Nelson, and Michael  
deMontbrun,

Plaintiffs,

v.

TAP Pharmaceutical Products Inc., et al.


Defendants.

**ORDER ON PLAINTIFFS' MOTION FOR  
PARTIAL SUMMARY JUDGMENT**

THIS CAUSE coming on to be heard and being heard before the Undersigned Judge, assigned to this case by the Chief Justice pursuant to Rule 2.1, on Plaintiffs' Motion for Partial Summary Judgment. The Court, having heard arguments of counsel for Plaintiffs and counsel for defendant TAP Pharmaceutical Products Inc. ("TAP") and reviewed all written material submitted to the Court, is of the opinion that Plaintiffs' motion for partial summary judgment on Counts II (claim for fraud), III (claim for civil conspiracy), and VI (claim for consumer fraud under N.C. Gen. Stat. § 75-1.1) should be denied.

THEREFORE, IT IS ORDERED, ADJUDGED AND DECREED, and Plaintiffs' Motion for Partial Summary Judgment is hereby DENIED.

This 9<sup>th</sup> day of March, 2004.

  
The Honorable Paul L. Jones  
Superior Court Judge  
Presiding, Pursuant to Rule 2.1

A TAPPALETT  
CLERK OF SUPERIOR COURT  
NEW HANOVER COUNTY  
BY: JANE D. JONES  
Clerk of Court

# EXHIBIT 9

OCT 09 2001

Office of the Superior Court Clerk  
by Deputy Clerk of the Superior Court  
CHARLES E. [illegible]  
Case 2-1-12257

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Attorneys for Plaintiff and the Class

OCT 12 2001

BERNARD WALKER, individually,  
and on behalf of those similarly situated,  
122 Reef Drive  
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Plaintiff,

v.

TAP PHARMACEUTICAL PRODUCTS,  
INC., ABBOTT LABORATORIES AND  
TAKEDA CHEMICAL INDUSTRIES,  
LTD.,

Defendants.

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION  
CAPE MAY COUNTY

DOCKET NO. CPM L - 682-01

Civil Action

CLASS ACTION COMPLAINT AND  
JURY DEMAND

Plaintiff, by his attorneys, brings this Complaint on his own behalf and on behalf of all others similarly situated to obtain declaratory and injunctive relief, damages, costs of suit, and attorneys' fees from the defendants. Plaintiff complains and alleges, upon information and belief, as follows:

#### NATURE OF ACTION

1. This case is brought by Plaintiff Bernard Walker as a class action on behalf of potentially thousands of individuals and entities to recover monies overpaid as a result of Defendants' fraudulent scheme that targeted Medicare Patients and potentially others.



Defendants are Abbott Laboratories ("Abbott"), Takeda Chemical Industries LTD ("Takeda") and TAP Pharmaceutical Products, Inc. ("TAP") (a wholly owned joint venture of Abbott and Takeda and prior to April 2000 known as TAP Holdings, Inc.) [collectively referred to herein as "Defendants"]. Defendants are manufacturers and sellers of drug known as Lupron® who have pleaded guilty to federal criminal and civil charges of violating the Prescription Drug Marketing Act ("PDMA") by, *inter alia*, artificially setting and fixing the prices of Lupron® sold in the United States, including New Jersey. Because of Defendants' unlawful conduct, Plaintiff and Class members paid artificially inflated prices for Lupron®.

2. During the period from at least 1991 through at least 1998, the exact dates of which are unknown by Plaintiff at this time, Defendants created and implemented a fraudulent marketing, pricing and sales scheme to defraud Lupron® patients by substantially increasing the sales of Lupron® and reaping unlawful profits at the expense of Medicare patients and potentially others who took Lupron. Among other things, Defendants systematically, among themselves and with other entities and individuals, created a pervasive illegal system to cause Medicare and Medicare Part B patients to overpay substantial amounts of money for the specific purpose of increasing the market share of Lupron® and maximizing their profits at the expense of Plaintiff and the Class. The improper marketing, pricing and sales practices relate to, *inter alia*, the following: (a) deliberately overstating the average wholesale price ("AWP") for Lupron®, the rate upon which Medicare reimbursement and Medicare beneficiaries' co-payments are set, so that both Medicare and Medicare patients paid artificially inflated amounts of money for Lupron®; (b) providing free samples of Lupron® to medical providers and instructing them that they could and should bill Medicare and Medicare patients for such free

samples; and (c) providing other unlawful financial inducements to medical providers to prescribe Lupron® causing Plaintiff and members of the Class to pay artificially inflated prices for Lupron®.

3. On or before October 3, 2001, Defendants agreed to plead guilty to having fraudulently priced and marketed Lupron. In particular, Defendants, by and through their joint venture, TAP, agreed to plead guilty to a conspiracy to violate the PDMA and agreed to pay a \$290 million criminal fine, the largest criminal fine ever in a U.S. health-care fraud prosecution case, according to the United States Department of Justice. Additionally, Defendants agreed to settle criminal and civil claims brought by the federal government for \$875 million, which amount consisted of the \$290 million criminal fine, \$559.5 million in civil liabilities for filing false and fraudulent claims, and \$25.5 million in civil liabilities to fifty states and the District of Columbia.

4. Defendants' conspiracy consisted of, *inter alia*, engaging in the practice of deliberately inflating the AWP, which is used by Medicare for reimbursement. The "spreads", consisting of the difference between what Defendants set as the AWP and the actual lower average wholesale price for non-Medicare usage, were used by Defendants to create a profit based incentive for medical providers to prescribe Lupron®.

5. The scheme allowed Defendants to control, as part of their sales and marketing strategies, how much reimbursement would be made under Medicare for Lupron®. Defendants deliberately marketed and promoted the sale of Lupron® and other Medicare covered drugs based on the availability of inflated payments made by Medicare and Medicare beneficiaries. The inflated payments—the amount Defendants set as the AWP exceeded the actual cost of

Lupron® to the medical provider—was often referred to by the Defendants in internal documents as “spread,” “return-to-practice,” “return-on-investment,” and “profit.” Defendants even prepared side-by-side comparisons of the spreads available on Lupron® versus their competitors drug. These comparisons were used as a marketing and sales pitch to medical providers. As a result, senior citizens, disabled individuals and others who depend on Medicare to pay a portion of their health care costs have paid millions of dollars in inflated drug prices.

6. Twenty percent (20%) of these inflated Medicare payments come directly from Plaintiff and Class Members’ pockets through co-payments and deductibles. In fact, there are many instances where the 20% co-payment paid by a beneficiary for a Medicare covered drug exceeded the actual cost of the drug to the health care provider.

7. Several urologists have pled guilty to Federal Criminal Informations charging them with conspiring with TAP to defraud Medicare and ultimately the Class regarding the usage of Lupron®. According to the Informations, Defendants provided medical providers with free samples and other financial incentives as inducements to increase the usage of Lupron®. *See, e.g., United States of America v. Spinella*, (D.Mass. Dec. 8, 2000); *United States of America v. Mannion*, (D.Mass. Feb. 28, 2000); *United States of America v. Zamstein*, (D.Mass. Nov. 3, 2000); *United States of America v. Olstein*, (D.Mass. April 11, 2001) (“Criminal Informations”).

8. Moreover, on April 20, 2001, Abbott filed a Form B-K wherein it disclosed:

Abbott Laboratories today announced an adjustment in litigation reserves to reflect recent developments related to the U.S. Department of Justice investigation into the marketing and sales practices of TAP Pharmaceutical Products Inc. for Lupron®. TAP Pharmaceutical Products Inc. is a 50/50 joint venture between Abbott and Takeda Chemical Industries, Ltd. Discussions between TAP and the Department of Justice are ongoing. The government’s inquiry has focused solely on marketing and sales

practices, and does not involve the safety and efficacy of Lupron®. This one-time adjustment in the litigation reserves will cause an adjustment to previously announced first quarter results, as reflected in the attached table. While it is not feasible to predict the outcome of this proceeding with certainty, no material impact on operations, or additional one time charges are expected.

9. The United States Government sought to recover only its portion of the fraudulent charges, which represents 80% of the overpayments caused by Defendants. Absent this litigation, neither Plaintiff nor the members of the Class will recover from Defendants the remaining 20% overpayments they made contained in the co-payment and/or deductible amounts they paid for Lupron®.

10. The Plaintiff has asserted claims under the common law and statutes of New Jersey and other states, as well as the District of Columbia.

#### JURISDICTION AND VENUE

11. Plaintiffs brings this action pursuant to consumer protection statutes and common law.

12. This Court has jurisdiction over Defendants because they are corporations regulated under the laws of the State of New Jersey and do sufficient business in, have sufficient minimum contacts with, or otherwise intentionally avail themselves of the markets of the State of New Jersey through the promotion, marketing, and sale of use of Lupron® in New Jersey.

13. Venue is proper in this Court since Plaintiff, as well as the numerous class members, purchased Lupron® from doctors and hospitals located in this County and New Jersey and otherwise engaged in the transactions which form the basis of this action by having paid for Lupron®. Plaintiff Bernard Walker is a resident of Cape May County and his claim does not exceed \$75,000.00.

### PARTIES

14. Plaintiff, Bernard Walker, is an individual and resident of the State of New Jersey who resides at 122 Reef Drive, Ocean City, Cape May County, New Jersey. Mr. Walker was diagnosed with prostate cancer in 1995 and was prescribed Lupron® for the treatment of his cancer by his treating physicians. Mr. Walker has taken Lupron® up to the present time and made several purchases of Lupron® in New Jersey. Mr. Walker has Medicare which paid for 80% of his Lupron® prescription purchases. The remaining 20% co-payment was paid in part directly by Mr. Walker. Accordingly, Mr. Walker suffered direct injury and damages as a result of Defendants' unlawful conduct set forth herein.

15. Defendant Abbott Laboratories ("Abbott") is a highly diversified health care company whose principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products and services. Abbott's business includes pharmaceuticals, nutritionals, hospital products, and diagnostics. Abbott's world headquarters are located in Abbott Park, Illinois. The company employs over 60,000 people and reported sales of \$13.7 billion for the fiscal year ended December 31, 2000.

16. Defendant Takeda Chemical Industries LTD ("Takeda") is Japan's largest pharmaceutical company and is among the largest in the world. Headquartered in Osaka, Japan, Takeda discovers, develops, manufactures and markets a broad range of pharmaceutical products. Takeda Pharmaceuticals America was created to take advantage of Takeda's growing, international pharmaceutical presence. Takeda Pharmaceuticals America's U.S. headquarters are in Lincolnshire, Illinois. Takeda's net sales for Financial Year 1999 were \$8.7 billion.

17. Defendant TAP Pharmaceutical Products, Inc. ("TAP") is a partnership between Takeda and Abbott. Under a partnership agreement between Abbott and Takeda, TAP (owned 50 percent by Abbott and 50 percent by Takeda), together with its subsidiary, TAP Pharmaceuticals, Inc., develops and markets pharmaceutical products for the United States and Canada. One of these products is Lupron® (an LH-RH analog) and Lupron Depot® (a sustained release form of Lupron®). Lupron® and Lupron Depot® (collectively referred to as "Lupron") are used principally for the palliative treatment of advanced prostate cancer, for the treatment of endometriosis, central precocious puberty and for the preoperative treatment of patients with anemia caused by uterine fibroids.

18. According to Abbott's recent Form 10-K filed February 15, 2001, Lupron® is sold directly to physicians, retailers, wholesalers, health care facilities, and government agencies. It is distributed from Abbott-owned distribution centers. TAP's primary marketing efforts are focused on securing the use of Lupron® by physicians. In 1998, the total revenues from Lupron® sales through Medicare was \$584 million consisting of 80% paid by the federal government (\$467 million) and 20% paid by Plaintiff and the Class Members (\$117 million). TAP's total sales revenue in 1998 was \$2.06 billion.

#### **PLAINTIFF'S CLASS ALLEGATIONS**

19. Plaintiff seeks to bring this case as a class action on behalf of himself and all others similarly situated in New Jersey and throughout the United States as members of a proposed class, defined as follows:

All persons and entities in New Jersey and throughout the United States who paid any portion of the cost of Lupron®. Excluded from the class are Defendants, any entity in which Defendants

have a controlling interest, and their legal representatives, heirs, successors and any governmental entities.

### NUMEROSITY

20. The proposed class is so numerous that joinder of all of its members is impractical. Thousands of patients each year are prescribed and pay for Lupron®.

### Common Questions of Law and Fact

21. Virtually all of the issues of law and fact in this class action are common to the class and include at least the following:

- (a) Whether the Defendants engaged in the unlawful conduct and conspiracy as alleged herein;
- (b) Whether the Defendants unlawfully set the AWP for Lupron®;
- (c) Whether Defendants provided free samples of Lupron® and other financial inducements to doctors and health care providers;
- (d) Whether the Defendants engaged in a pattern and practice of deceiving and defrauding the Class and suppressing their unlawful conduct and conspiracy;
- (e) Whether the defendants violated state consumer protection statutes;
- (f) Whether Plaintiff and the members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;
- (g) Whether Plaintiff and the members of the Class are entitled to punitive or exemplary damages and, if so, the nature of such damages; and
- (h) Whether Plaintiff and members of the Class are entitled to an award of reasonable attorneys' fees, prejudgment interest, post-judgment interest and costs of suit.



**Typicality**

22. Plaintiff's claims are typical of the Plaintiff's Class members' claims. Plaintiff and all members of the Class sustained damages. The financial losses of each member of the class were directly caused by the Defendants' unlawful conduct and conspiracy.

**Adequacy of Representation**

23. Plaintiff can and will fairly and adequately represent and protect the interests of the class and has no interests that conflict with or are antagonistic to the interests of class members. Plaintiff has retained attorneys competent and experienced in class actions, including consumer product class actions. No conflict exists between Plaintiff and the Class members.

**Superiority**

24. A class action is superior to any other available method for the fair and efficient adjudication of this controversy and common questions of law and fact overwhelmingly predominate over any individual questions that may arise.

- (a) The prosecution of separate actions by individual members of the Plaintiff's Class would create a risk of inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the Defendants or adjudication with respect to individual members of the Class which would as a practical matter be dispositive of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.
- (b) The Defendants have acted or refused to act on grounds generally applicable to all members of the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole.